

REMARKS

Reconsideration and withdrawal of the rejection and the allowance of all claims now pending in the above-identified patent application (*i.e.*, Claims 29, 30 and 32-48) are respectfully requested in view of the foregoing amendments and the following remarks.

At the outset, it should be recalled that the present invention provides hygienic protection for endoscopes, so that such instruments, which have become highly valuable medical diagnostic and procedure tools, can be readily re-used on a patient following recent use on a prior patient. Endoscopes, lacking proper protection against contamination, must generally be dismantled after each use and thoroughly cleaned, which is both time-consuming and quite expensive.

The present invention, as now claimed, provides hygienic protection for an endoscope, which includes a cover, which is closed at its distal end and which is transparent for optical information, at least on the front side thereof, with the cover able to be rolled or unrolled thereon in a direction of the axis of the endoscope, and including a material that is air-tight, watertight and impermeable to pathological microorganisms with connection of the cover to the working channel to the distal end of the cover being made airtight, watertight and impermeable to pathological microorganisms. One or more working channels for the endoscope extend in a parallel position in relation to the endoscope and terminate in an open manner on the distal end of the cover – the working channel being connected only to the distal end of the cover. The working channels are positioned between the outside of the endoscope and the inner side of the cover. There is only a

single vacuum channel, that is parallel to the working channel, having one or more openings, which terminates at the inside of the cover in a direction facing the endoscope, which is a “dedicated” vacuum and is in addition to the separate working channels. The vacuum channel is used for pressing the cover onto the endoscope upon the application of sub-atmospheric pressure, or suction, through the vacuum channel. As explicitly claimed, the working channel(s) and the single vacuum channel are entirely separate from one another, in that the one or more working channels are not useful for use as a vacuum channel, and vice versa, in contrast to the applied prior art.

More particularly, the single vacuum channel of the presently claimed invention terminates in an open manner within the envelope of the endoscope protection and can have additional side openings. These side openings advantageously terminate at the inside of the cover on the side of the cover (*i.e.*, an inner side or inner surface of the cover) facing in a direction of the endoscope. When a vacuum is applied to this channel, the air located between the cover and endoscope shaft is sucked out with the consequence being that the cover is drawn firmly, or pressed, onto the endoscope. The vacuum is then maintained during the examination. Thus, a fixed connection between the cover and endoscope is produced advantageously and rapidly after the endoscope has been introduced into the cover, which is dimensioned somewhat larger in the interior diameter, preferably in the proximal part.

During application of the hygiene protection, one hand of the medical practitioner fixes the freely movable working channels and the vacuum channel on the endoscope

shaft, while the practitioner's other hand rolls on the cover above the channels. The combination of a protective cover, with its own working channels, extends outside of the endoscope with the protective cover and the working channels being connected to one another in the distal region of the cover in an airtight and germ-free manner. For attachment of the protection cover in accordance with the presently-claimed invention, the distal end of the cover is pushed onto the endoscope, so that the front face, which is transmissible for optical information, is correctly positioned, *i.e.*, positioned parallel to the distal end of the endoscope. The optical contact between the endoscope and the transparent front face of the cover is preferably produced by means of a fluid, such as microscope immersion oil, which ideally has the same refractive index as the lens of the endoscope.

As will be explained in greater detail hereinafter, nowhere in the prior art is such a novel and hygienically effective protection apparatus and related method for an endoscope, having one or more separate working channels and single, dedicated vacuum channel, which is aligned parallel to the one or more working channels, for enhanced hygiene, in which the openings of the vacuum channel terminates at the inside of the cover of the endoscope protection at an inner side of the cover facing in a direction toward the endoscope and is used for drawing, or pressing, the cover onto the endoscope, either disclosed or suggested.

By the present amendments, Applicant has amended independent Claims 29 (and Claims 30 and 32-46 via dependency), 47 and 48 to now recite that the single vacuum

channel is --parallel to said working channel--, which represents a feature not disclosed in the prior art and would be inconsistent with the applied prior art laryngoscope apparatus of Vescovo, Jr., U.S. Patent No. 4,972,825, as discussed in greater detail hereinafter.

Applicant has further amended, in a non-substantive manner, independent Claim 29 to delete reference to “said working channel” in the first sub-paragraph of this claim and add the deleted language to the second sub-paragraph, which positively introduces “a working channel” into Claim 29, thereby providing a proper antecedent basis for all claim elements of independent Claim 29 and those claims dependent thereon.

In the latest Office Action, the Examiner had rejected Claims 29, 30 and 32-46 as being indefinite, pursuant to 35 U.S.C. §112, second paragraph, on the ground that “said working channel,” first appearing at line 5 of Claim 29, lacked a proper antecedent basis. The amendment referenced in the preceding paragraph is submitted to overcome the Examiner’s 35 U.S.C. §112, second paragraph, indefiniteness rejection, which should now be appropriately withdrawn.

Accompanying the present *Amendment in Response to the Final Office Action*, Applicant is filing a *Request for Continued Examination* and formal *Petition for a Three-Month Extension of Time* for response, and remitting all required fees. Accordingly, the “finality” of the last Office Action should be withdrawn and the foregoing amendments presented herein entered, and considered on their merits, as a matter of right.

Turning now, in detail, to an analysis of the Examiner’s prior art rejection, in the

“final” Office Action, issued December 7, 2010, the Examiner rejected independent Claims 29, 47 and 48 (and various dependent claims) as being obvious, pursuant to 35 U.S.C. §103(a), over Silverstein *et al.*, U.S. Patent No. 4,646,722, on the overall contention that Silverstein *et al.* discloses an endoscope (and related method) for hygiene protection, that includes a cover that is closed at a distal end and transmissible for optical information, a working channel extending parallel and being connected only to the distal end of the cover and positioned between an outer side of the endoscope via an inside of the cover, and a vacuum channel having at least one opening and terminating at the inside of the cover. The Examiner has also contended that Silverstein *et al.* teaches that the vacuum channel “is a different channel 64 from said working channel.” The Examiner has, however, conceded Silverstein *et al.* fails to positively disclose but a single vacuum channel, as Applicant claims, having at least one opening and terminating at the inside of the cover of the opening and terminating inside of the cover in a direction facing the endoscope for pressing the cover onto the endoscope via application of sub-atmospheric pressure. The Examiner has therefore secondarily-applied, newly-cited Vescovo, Jr., U.S. Patent No. 4,972,825 for its contended teaching of a single vacuum that discloses the feature admittedly absent from Silverstein *et al.*, thereby concluding that it would have been obvious to have modified the single vacuum channel (64) of Silverman *et al.* and the cover (10, 30, 48) of the primarily-applied reference with the single vacuum channel (33) and its connection with a cover (11, 13), as taught by Vescovo *et al.*, in order to have provided an improved endoscope with hygiene protection and having a single vacuum channel that is capable of efficiently removing air from the interior of the

cover via a source of sub-atmospheric pressure in order to allow the cover to collapse about the endoscope for maintaining sterility and sanitation of the endoscope, and other benefits.

In reply to the Examiner's 35 U.S.C. §103(a) obviousness rejection applying Silverstein *et al.*, taken in view of Vescovo, Jr., with reference to the primarily-applied citation of Silverstein *et al.*, the channel (36) therein is described (at Col. 7, lines 25-28) as being a "biopsy channel" (36), which is used to extract material from outside of the cover of the Silverstein *et al.* apparatus (*e.g.*, the removal of cells or tissues from the patient for an outside examination as a diagnostic tool.) The biopsy channel of Silverstein *et al.* is adapted to an entirely different purpose from that of the vacuum channel of the presently claimed invention, in addition to the structural distinction that the opening of the vacuum channel of the present invention is located inside of the cover.

The secondarily-applied reference of Vescovo, Jr. teaches a laryngoscope cover with a laryngoscope being a device used for obtaining a view of the vocal folds and glottis via one's mouth and is therefore necessarily quite short, as compared to such endoscopes as that of the presently claimed invention. For such a "short endoscope," Vescovo, Jr. describes a relatively wide cover, which can be successfully deflated by way of only a single opening. Structurally, Vescovo, Jr. discloses a tubular member (33), which is connectable to a source of suction and is equated to a vacuum channel, which is intended to withdraw air from the interior (15) of the body (13) to collapse about the laryngoscope (L) of Vescovo, Jr. (at Col. 3, lines 5-10), and which cannot be seen as

being parallel to any analogous working channel, as Claims 29, 47 and 48 have now been amended to recite.

Considering Silverman *et al.* in combination with Vescovo, Jr., the primarily-applied citation teaches a biopsy channel having suction applied thereto which is located outside of the analogous cover, while Vescovo, Jr., which teaches a cover relevant to laryngoscope, includes a vacuum channel that is intended for a different purpose and cannot be said to be “parallel” to any working channel, as now claimed by Applicant. Combining the two applied citations would therefore not yield that now recited in Applicant’s independent Claims 29, 47 and 48, neither structurally nor taking into consideration the vastly differing intended uses of the prior art devices, which is submitted to be a valid consideration in an obviousness determination, as opposed to addressing an anticipation rejection. *See, United States v. Adams*, 383 U.S. 39, 148 USPQ 479, 484 (1966) (“This is not to say that one who merely finds new uses for old inventions by shutting his eyes to their prior disadvantages thereby discovers a patentable innovation. We do say, however, that known disadvantages in old devices which would naturally discourage the search for new inventions may be taken into account in determining obviousness.”); 2 Rosenberg, P. D., Patent Law Fundamentals, §9.04 at 9-45 (2d Ed., 1993 rev.) (“Where the claimed structure is simple and/or differs slightly from the prior art, the inquiry may focus upon the utility or result effected.”).

Accordingly, withdrawal of the Examiner’s 35 U.S.C. §103(a) obviousness rejection applying Silverstein *et al.*, taken in view of Vescovo *et al.*, against independent

Claims 29, 47 and 48 is respectfully submitted to be proper.

In view of the foregoing, it is respectfully contended that all claims now pending in the above-identified patent application (*i.e.*, Claims 29, 30 and 32-48) recite a novel and hygienically effective protection apparatus and related method for an endoscope, having one or more separate working channels and single, dedicated vacuum channel for enhanced hygiene which is aligned parallel to the working channels, and in which the openings of the vacuum channel terminates at the inside of the cover of the endoscope protection at an inner side of the cover facing in a direction toward the endoscope, which is patentably distinguishable over the prior art. Accordingly, withdrawal of the outstand-

ing rejection and the allowance of all claims now pending are respectfully requested and earnestly solicited.

Respectfully submitted,

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Enc.: 1. Petition for Three-Month Extension of Time for Response;
2. *Request for Continued Examination*, pursuant to 37 C.F.R. §1.114; and,
3. EFT for \$960.00 (*Request for Continued Examination* filing fee +
Three-Month Extension Fee).

The Commissioner for Patents is hereby authorized to charge the Deposit Account of Applicant's Attorney (Account No. 19-0450) for any fees or costs pertaining to the prosecution of the above-identified patent application, but which have not otherwise been provided for.